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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,550	01/26/2001	Komei Washino	Q62780	9592

7590

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/744,550

Applicant(s)

WASHINO ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-14 are pending.

#### ***Specification***

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

#### ***Claims***

Claims 6-14 are in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 1-14 provide for the use of a drug, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

(ii) The phrase “characterized by containing” in claim 1 (line 1) is vague and indefinite, as it is not clear whether the drug has the limitations that follow the phrase “characterized by containing” or if the drug is similar to drugs having the limitations that follow the phrase “characterized by containing”.

(iii) The phrase “a compound which carries in its chemical structure” in claim 1 (lines 2-3) is vague and indefinite, as it is not clear how a compound carries something. Does it mean bonded to? What does it mean?

(iv) The phrase “the relaxation effect is spreaded” in claims 1 (line 6) and 14 (line 9) is vague and indefinite, as it is confusion. How is a relaxation state “spreaded”? What is “spreaded”?

(v) The phrase “above-mentioned proton” in claims 1 (line 9) is vague and indefinite, as it is confusing. Does it mean the proton bound to the  $^{17}\text{O}$ ,  $^{14}\text{N}$  or  $^{33}\text{S}$ , or does it mean the proton in the vital component?

(vi) The phrase “therapeutic agents, nutritional or tonic agents, agents for blood and humor, and agents for diagnosis” in claim 3 (lines 3-4) is vague and indefinite. These agents are not defined in the specification and one of ordinary skill in the art would not be apprised of them.

(vii) The phrase “wherein the agent for blood and humor is infusion” in claim 4 is vague and indefinite, as it is confusing. Is infusion a drug? Is infusion a description of something? What is it?

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(viii) Claim 6 is vague and indefinite, as it is confusing. Is not the compound comprising the 17OH, 14NH or 33SH the drug? Why is described as the drug, the active ingredient, the additive, and the solvent?

(ix) The phrase “wherein the drug has been processed with a material for a drug delivery system” in claim 12 is vague and indefinite, as it is confusing. What does it mean to process a drug? What are materials for drug delivery systems? The specification does not further define this phrase and one of ordinary skill would not be apprised of its meaning.

(x) The phrase “compound carrying in its chemical structure” in claims 6 (line 2) and 14 (lines 2-3) is vague and indefinite, as it is not clear how a compound “carriers”. Does it mean that the compound is bonded to the components recited in the claim? What does it mean?

(xi) Claim 14 is vague and indefinite, as it is confusing. What does it mean to enable the determination of something? What is being determined?

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopkins et al. (Mag. Res. In Med.).

Hopkins et al. teach oxygen-17 compounds as potential NMR T2 contrast agents and the effects of H2-17O on protein solutions and living tissues. See pgs. 399-403.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et al. (Mag. Res. In Med.) in view of Unger (6,088,613).

Hopkins et al. is applied as discussed above. The reference fails to teach infusion, sugars, amino acids, aqueous solvents, and drug delivery systems.

Unger teaches a method of magnetic resonance focused surgical and therapeutic ultrasound. Disclosed are contrast mediums comprising a gas or gaseous precursor filled vesicle, and optionally a therapeutic compound. The vesicle is disclosed as a lipid bilayer (also known as a liposome). 17-Oxygen is disclosed as a gas for use in the composition. Glucose and amino acids are disclosed as stabilizers for the gas filled vesicles. Aqueous diluents are also disclosed. See Col. 3, line 31-Col. 7, line 8; Col. 13, line 6-line 37; Col. 17, line 37-Col. 28, line 37.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the oxygen-17 gas filled vesicles of Unger for the oxygen-17 compounds of Hopkins et al. because a) both Hopkins and Unger teach oxygen-17 compounds for use as contrast agents; b) Unger teaches that his encapsulated gas contrast agents are extremely effective and non-toxic; c) Unger teaches NMR as his preferred imaging modality; thus, since Unger utilizes his oxygen-17 gas filled vesicles for NMR one would expect the contrast agents of

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Unger and Hopkins to have similar properties; hence, the replacement of one for the other for imaging purposes would be within the skill of one in the art.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
February 7, 2002

  
**DAMERON L. JONES**  
**PRIMARY EXAMINER**